REMARKS/ARGUMENTS

Claims 20-37 and 48-49 are active. Claims 38-47 have been withdrawn from consideration. The claims have been amended in accordance with the Examiner's suggestions and for clarity. Support for the amendments is found in the original claims and in the disclosure. The Applicants do not believe that any new matter has been introduced.

Restriction/Election

The Applicants previously elected with traverse **Group I**, claims 20-37 and 48, directed to a method and kit for quantifying HMW-Ad. The requirement has been made FINAL. The Applicants respectfully request that the claims of the nonelected group(s) which depend from or otherwise include all the limitations of an allowed elected claim, be rejoined upon an indication of allowability for the elected claim, see MPEP 821.04.

The Applicants thank Examiner Cook for the courteous and helpful interview of December 4, 2008. The differences between the prior art methods and assays involving the selective digestion of adiponectin monomers were discussed. It was suggested that the Applicant further clarify the nature of the adiponectin proteolytic fragments disclosed in the prior art, such as the globular domain mentioned by Waki, et al. Claim language that would emphasize the differences between the prior art methods and the claims was discussed.

Priority

Correction of the specification to include continuing data for PCT/JP04/15260 was requested. The Applicants note that the required specific reference to a priority document may now be included in an ADS, see MPEP 201.11 (III). This priority document is already

described in the previously filed ADS. Therefore, this objection should now be withdrawn and the Applicant's priority claim properly acknowledged.

Information Disclosure Statement

The Applicants thank Examiner Cook for acknowledging the three information disclosure statements.

Specification—Objections

The specification was objected to as containing various informalities. This objection is moot in view of the amendments above.

Claims—Objections

The claims were objected to as containing particular acronyms. These acronyms would be clear to one of skill in the art when read in light of the specification, see the definitions of various adiponectin fractions on page 5 of the specification. Nevertheless, they have been defined in the claims in their first instances as recommended by the Examiner. Therefore, this objection may now be withdrawn.

Rejection—35 U.S.C. §112, second paragraph

Claim 21 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is moot in view of the amendment above.

Rejection—35 U.S.C. §102

Claims 20 and 31 were rejected under 35 U.S.C. §102(a) as being anticipated by Waki, et al., JBC 278:40352. Waki does not disclose or suggest selective digestion of at

least one type of adiponectin multimer as a means for quantifying an amount of a target multimer (i.e., the elected species: HMW adiponectin).

Waki, page 40353, 2nd col., describes trypsin (proteolytic) digestion of wild-type adiponectin, which digests all naturally occurring adiponectin species into a globular domain. The globular domain of Waki is not a naturally occurring product and, thus, does not correspond to the naturally occurring adiponectin multimers (e.g., HMW, MMW, LMW species) recited by the present claims. Indeed, the globular domain of Waki is not an adiponectin multimer at all. Thus, while Waki discloses trypsin digestion, it does not disclose or contemplate quantifying the amount of HMW adiponectin by selectively digesting a sample suspected of containing HMW-adiponectin. Accordingly, it cannot anticipate these claims and this rejection cannot be maintained.

Rejection—35 U.S.C. §103(a)

Claims 21-30 and 32-37 were rejected under 35 U.S.C. §103(a) as being unpatentable over Waki, et al., JBC 278:40352., in view of Kondo, et al., Diabetes 51:2325. This rejection is moot in view of the cancellation of the prior claims or the amendments above.

While Waki discloses HMW adiponectin multimers (see abstract), it does not disclose or suggest selective digestion of at least one type of adiponectin multimer, in a method for quantifying the amount of HMW adiponectin in a sample.

Kondo has been relied upon for teaching "procedures which detect adiponectin in type 2 diabetes" (OA, bottom of page 7) on the grounds that particular proteolytic fragments of adiponectin ("a protease generated globular segment", OA, middle of page 8) modulate lipid and glucose metabolism. However, while Kondo may disclose adiponectin fragments, it is silent about quantifying HMW adiponectin using selective proteolytic digestion, e.g., selective digestion of certain forms of adiponectin, but not others.

In contrast, the invention provides a way for selectively quantifying adiponectins having different quaternary structures and different molecular masses. The invention provides a way to selectively assay for HMW adiponectin (as well as other forms of adiponectin) using selective proteolysis to distinguish between different forms of adiponectin. The prior art does not contemplate or suggest such a method.

Since the prior art documents do not disclose or suggest a method for selectively quantifying HMW adiponectin using selective proteclytic digestion, this rejection should now be withdrawn.

Rejection—35 U.S.C. §103(a)

Claim 48 was rejected under 35 U.S.C. §103(a) as being unpatentable over Waki, et al., JBC 278:40352., in view of Kondo, et al., Diabetes 51:2325, and further in view of Foster, et al., U.S. Patent No. 4,444,879. This rejection may be withdrawn for the reasons discussed above for Waki and Kondo. Foster was relied upon for teaching kits, but like the two other cited documents does not suggest selectively digesting one type of adiponectin multimer in a method for quantifying HMW adiponectin.

Conclusion

In view of the amendments and remarks above, the Applicants respectfully submit that this application is now in condition for allowance. An early notice to that effect is earnestly solicited.

Respectfully submitted,

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